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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,598	03/29/2001	Thomas M. Jessell	57477-A-PCT-US/JPW/MVM	5690

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,598	JESSELL ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1, 6, 14, 16, 18, 21, 24, 27, 34, 38, 44, 45, 48-50, 52, 56, 57, 60, 61, 66, 74, 76, 78, 81, 84, 87, 94, 104, 108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1,6,14,16,18,21,24,27,34,38,44,45,48-50,52,56,57,60,61,66,74,76,78,81,84,87,94,104 and 108.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1, 6, 14, 16, 18, 21, 24, 44, drawn to isolated nucleic acids encoding an MNR2 protein and a method of making the protein, classified in class 435, subclass 69.1.
2. Claims 27 and 48, drawn to a purified MNR2 protein, classified in class 530, subclass 350.
3. Claim 34 drawn to an antibody directed to an MNR2 epitope, classified in class 530, subclass 387.1.
4. Claims 38, drawn to a method of inducing differentiation in somatic motor neurons by expressing MNR2 protein in neural progenitor cells, classified in class 514, subclass 44.
5. Claims 45, 49, 50, 52, and 60, drawn to methods of inducing differentiation in somatic motor neurons by administering a purified MNR2 protein, classified in class 514, subclass 2.
6. Claims 56 and 57, drawn to methods of diagnosing chronic neurodegenerative disease by detecting MNR2 nucleic acids, classified in class 435 subclass 6.

7. Claims 61, 66, 74, 76, 78, 81, 84, and 104, drawn to isolated nucleic acids encoding HB9, and a method of making HB9 protein, classified in class 435, subclass 69.1.

8. Claims 87 and 108, drawn to a purified HB9 protein, classified in class 530, subclass 350.

9. Claims 94, drawn to an anti-HB9 antibody, classified in class 530, subclass 387.1.

10. Claims 98, 121, 123 drawn to methods of treatment by delivering MNR2 nucleic acids, classified in class 514, subclass 44.

11. Claims 105, 108-110, 112, 120, 122 and 124, drawn to methods of treatment by administering a purified HB9 protein, classified in class 514, subclass 2.

12.. Claims 116 and 117, drawn to methods of diagnosing chronic neurodegenerative disease by detecting HB9 nucleic acids, classified in class 435 subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-6 are unrelated to invention 7-12 because inventions 1-6 pertain to MNR2 nucleic acids, proteins, and antibodies, whereas Inventions 7-12 pertain to HB9 nucleic acids, proteins, and antibodies. MNR2 and HB9 are structurally and functionally distinct polypeptides (see e.g. page 6, lines 10-14 of the specification), so their nucleic acids and antibodies are necessarily structurally and functionally distinct.

Inventions 1, 2, and 3 are distinct from each other. The polynucleotides of Invention 1 are distinct in chemical structure and function, as well as therapeutic function, from the polypeptides of Invention 2 and the antibodies of Invention 3. Additionally, polynucleotides, polypeptides, and antibodies can be used by materially different methods. Polynucleotides can be used as detection probes, polypeptides can be used for antigen presenting cell priming and antibodies can be used in screening assays, for example. The differences between Invention 1 and Inventions 2 and 3 are further underscored by their divergent classification and independent search status.

Inventions 1 and 4 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used in a materially different process such as a hybridization assay to detect MNR2.

Inventions 1 and 5 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention 1 is a composition that cannot be used in the method of invention 5, nor is it produced by the method. So, the inventions have different functions, and effects and are not disclosed as capable of use together.

Inventions 1 and 6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used in a materially different process such as production of MNR2 protein.

Inventions 2 and 3 are unrelated to inventions 4 and 6. The protein and antibody of inventions 2 and 3 are not disclosed as being used in the diagnostic and therapeutic nucleic acid-based methods of inventions 4 and 6.

Inventions 2 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of invention 2 can be used in a materially different process such as the production of antibodies.

Inventions 3 and 5 are unrelated. The antibody of invention 3 is not disclosed as being used in the therapeutic method of invention 5, nor is it produced or in any way affected by the assay.

Inventions 4-6 are unrelated to each other. For example, inventions 4 and 5, while both resulting in the same endpoint, arrive there through different method steps requiring structurally and functionally different reagents. Inventions 4 and 5 are not

diagnostic methods, as is invention 6, and cannot be used for diagnosis. Likewise invention 6 cannot be used for therapy.

Inventions 7, 8, and 9 are distinct from each other. The polynucleotides of Invention 7 are distinct in chemical structure and function, as well as therapeutic function, from the polypeptides of Invention 8 and the antibodies of Invention 9. Additionally, polynucleotides, polypeptides, and antibodies can be used by materially different methods. Polynucleotides can be used as detection probes, polypeptides can be used for antigen presenting cell priming and antibodies can be used in screening assays, for example. The differences between Invention 7 and Inventions 8 and 9 are further underscored by their divergent classification and independent search status.

Inventions 7 and 10 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used in a materially different process such as a hybridization assay to detect HB9.

Inventions 7 and 11 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention 7 is a composition that cannot be used in the method of

invention 11, nor is it produced by the method. So, the inventions have different functions, and effects and are not disclosed as capable of use together.

Inventions 7 and 12 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the HB9 nucleic acids can be used in a materially different process such as production of HB9 protein.

Inventions 8 and 9 are unrelated to inventions 10 and 12. The protein and antibody of inventions 8 and 9 are not disclosed as being used in the diagnostic and therapeutic nucleic acid-based methods of inventions 10 and 12.

Inventions 8 and 11 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of invention 8 can be used in a materially different process such as the production of antibodies.

Inventions 9 and 11 are unrelated. The antibody of invention 9 is not disclosed as being used in the therapeutic method of invention 11, nor is it produced or in any way affected by the assay.

Inventions 10-12 are unrelated to each other. For example, inventions 10 and 11, while both resulting in the same endpoint, arrive there through different method steps requiring structurally and functionally different reagents. Inventions 10 and 11 are not diagnostic methods, as is invention 12, and cannot be used for diagnosis. Likewise invention 12 cannot be used for therapy.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.